



UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

July 29, 2016

**MEMORANDUM**

Subject: Efficacy Review for Capricorn,  
EPA Reg. File No. 10772-EG,  
DP Barcode: D432547

From: Son Nguyen  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

To: Julie Chao, RM33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Church & Dwight Co., Inc.  
500 Charles Ewing Blvd.  
Ewing, NJ 08628

**Formulation from the Label:**

<u>Active Ingredient</u>	<u>% by wt.</u>
Sodium Percarbonate.....	18.50
Tetraacetylenediamine.....	4.44
<u>Other Ingredients</u> .....	<u>77.06</u>
Total .....	100.00%

## **I. BACKGROUND**

The product, Capricorn (EPA Reg. File #10772-EG) is a new product, designed as a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant (bactericide, virucide) and sanitizer for use in sites such as homes, schools, hospital and office buildings. The studies were conducted at Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 8, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 24 new efficacy studies (MRID Nos. 49795317 through 49795340), and the product's proposed label. Statement of No Data Confidentiality Claims, Compliance Statement and Quality Assurance Unit Summary were included with each study.

Note: On Nov. 10, 2015, the Agency confirmed via email that the contact times for laundry sanitization at 10 minutes and laundry disinfection at 15 minutes are acceptable claims for this product. (Emails attached with submission package).

## **II. USE DIRECTIONS**

The product is designed for use on hard, non-porous surfaces, such as appliance exterior, bathtub [tub], bed frame, cabinet [non-wood], chair [non-wood], changing table [non-wood], counter [countertop], crib [non-wood], diaper pail [non-wood], exhaust [fan] [hood], faucet, fixture [chrome/stainless steel], floor [linoleum], floor [glazed ceramic/porcelain tile], floor [laminated], floor [sealed marble], floor [vinyl], garbage [can] [pail] [container], glazed ceramic tile, glazed porcelain tile, grill [barbecue] exterior, highchair [non-food contact area], microwave exterior, non-medical [chrome/stainless steel], outdoor patio furniture [non-wood], oven [door], patio door, picnic table [non-wood], plastic laundry [basket] [hamper], range hood [stove hood], refrigerator shelves [drawers], sealed granite, shower [door] curtain, shower [stall] [area], sink [basin], stove [stovetop], table [tabletop] [non-wood], telephone, toilet bowl exterior [urinal], water fountain, window [windowsill], vanity top. The product can be used on hard, non-porous surfaces materials, such as chrome, Corian, countertop, crystal, enamel, Formica, glazed ceramic, glazed granite, glazed porcelain, glazed tile, laminate, linoleum, plastic laminate, sealed fiberglass fixtures, sealed marble, Silestone, stainless steel, vinyl. The product is also designed to be used on soft surfaces, such as baby carriages, baby prams, backpack/schoolbag, bathroom mat, bedding [bedspread], box spring [cover], car [seat] [upholstery], clothing, cotton [fabrics] purse, cots, couch [sofa], curtains [draperies], cushion [pillow], dog [pet] bed, diaper bag, duvet cover, gym bag [fabric], [upholstered] highchair seat, laundry bag [fabric], mattress [cover], mop [broom], seat cushion [household], seat cushion [kitchen], shoes [canvas] [fabric], shoe interior, shower curtain [fabric], slippers, sneakers [canvas] [fabrics], sponges [rags], sport(s) [bag(s)] [equipment], soft [fabric] surfaces, stroller [seats], stuffed [plush] toys, suitcase [luggage], throw rug, [upholstered] booster seat, [upholstered] chairs, [upholstered] couches, [upholstered] furniture, upholstery, window treatment [fabric].

Directions on the proposed label provide the following information regarding preparation and use of the product:

#### Testing and Dilution Type:

Testing Type	Type of Organism	Dilution Type	Efficacy Study	Gallon Conversion
Hard Surface	Bacteria	2X	62.4 grams Product / 1 liter	236 grams Product / 1 gallon water
	Viruses			
Hard Surface	Fungi	2X	62.4 grams Product / 1 liter	236 grams Product / 1 gallon water
Non-Food Contact	Bacteria	1X	31.2 grams Product / 1 liter	118 grams Product / 1 gallon water
Soft Surface	Bacteria	2X	62.4 grams Product / 1 liter	236 grams Product / 1 gallon water
Soft Surface	Fungi	2X	62.4 grams Product / 1 liter	236 grams Product / 1 gallon water
Laundry Pre-Soak	Bacteria	1X	31.2 grams Product / 1 liter	118 grams Product / 1 gallon water
	Viruses			
Laundry Pre-Soak	Bacteria	1X	31.2 grams Product / 1 liter	118 grams Product / 1 gallon water

#### [LAUNDRY] [SANITIZATION] [and] [DISINFECTION]

[To] Sanitize [Laundry]:

[Pre-soak [Use]:] {Insert directions for “1X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}[in washing machine]. Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

[To] Disinfect [Laundry]:

[To kill] bacteria and viruses†[:] {Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)} [in washing machine]. Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

#### HARD NON-POROUS [SURFACES]

[To] Sanitize [Hard Surfaces]:

[1] {Insert directions for “1X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.

[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.]

[To] Disinfect [Hard Surfaces]: [1] Pre-clean surface.

[2] {Insert directions for “2X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] [min.] for viruses†.

[4] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop].

[To] Prevent Mold [and Mildew]:

[1] {Insert directions for “2X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.

[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth].

## **SOFT SURFACES [AND] [&] [FABRICS]**

[To] [Spot] Sanitize [Soft Surfaces]:

[1] {Insert directions for “2X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.

[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric]:

[1] {Insert directions for “2X” dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.

[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against *Aspergillus* [A.] *niger* [(black mold)] [mildew] and *Penicillium* [P.] variable.

## **III. AGENCY STANDARDS FOR PROPOSED CLAIMS**

### Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested against each of the three batches of the product at lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of  $1.0 \times 10^6$ ) and not above 7.0 (corresponding to a geometric mean density of  $1.0 \times 10^7$ ) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. For AOAC Germicidal Spray Products Test, a mean log density of at least 5.0 (corresponding to a geometric mean density of  $1.0 \times 10^5$ ) and not above 6.5 (corresponding to a geometric mean density of  $3.2 \times 10^6$ ) for both organisms is required. A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as “disinfectants”, killing on 59 out of 60 carriers for germicidal spray testing is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results for both UDM and GST methods. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at  $\leq 10$  minutes of contact.

### Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):

Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in 10 minutes. The minimum carrier count to make the test valid should be  $1 \times 10^4$  CFU/carrier. For a valid test, no contamination of any carrier is allowed.

#### Virucides:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least  $10^4$  from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

#### Sanitizer Test (for inanimate, non-food contact surfaces):

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as “one-step sanitizers” should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least  $7.5 \times 10^5$  colony forming units per carrier. The performance measure should demonstrate a reduction of  $\geq 99.9\%$  (a 3-log<sub>10</sub> reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

#### Sanitizers (For Non-Food Contact Surfaces: Additional Bacteria):

Effectiveness of sanitizers for non-food contact surfaces against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. In these cases, confirmatory test standards would apply. The effectiveness of sanitizers for non-food contact surfaces against specific bacteria must be determined by the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153). Two product samples, representing 2 different product lots, should be tested against each additional microorganism. Use 5 test carriers and 3 control carriers. The ASTM method states that the inoculum employed should provide a count of at least  $7.5 \times 10^5$  colony forming units per carrier. The performance measure should demonstrate a reduction of  $\geq 99.9\%$  (a 3-log<sub>10</sub> reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

#### Spot Soft Surface Sanitization:

The study is designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial

efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03). Three product samples, representing three different batches, at the LCL should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states “an average of at least  $7.5 \times 10^5$  organisms must have survived the inoculated control squares for the test to be valid.” Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

#### Hard Surface Mildew Fungistatic Test:

This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Fabric Mildew Fungistatic Test Method: The test is to be conducted on cotton muslin strips cut 25 by 75 mm from 136 to 203 g/m<sup>2</sup> (4 to 6 oz./yd.<sup>2</sup>) fabric. The strips should be autoclaved sterilized. The product is to be tested against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Soak fabric strips in Nutrient broth for three minutes or until saturated. Remove excess liquid and allow fabric strips to dry before proceeding with application of the test product. Both sides of ten strips for each batch should be spray treated with product. The application specifications including spray distance from nozzle, degree of wetness, draining conditions, and drying procedures should be reported. Equal volumes of well-agitated conidial suspensions of *Aspergillus niger* and *Penicillium variable* using a DeVilbiss atomizer (or equivalent) should be sprayed on both sides of each fabric strip. The fabric samples are suspended in individual 500 mL jars containing 90 mL water and incubated at approximately 28°C with the caps tightened and backed off 1/8 turn to allow for ventilation. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The untreated control strips (10 strips) must have a minimum of 50% of their surface area covered with fungal growth after 7 days to consider the test valid. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks incubation must specify a retreatment schedule, such as “repeat as necessary when new growth appears”, and should indicate that treatments should be effective for at least 28 days.

#### Laundry Disinfectant – Pre-Soak Treatment for Use in Hospital or Medical Environments:

The effectiveness of disinfectants as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations in hospital or medical environments must be substantiated by data derived using the AOAC International Use-Dilution Method (Ref.1) (for water soluble powders and liquid products) modified to include 5% organic soil. Sixty carriers must be tested against each of the three batches of the product at the lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density of at least 6.0 (corresponding to a geometric mean density of  $1.0 \times 10^6$ ) and not above 7.0 (corresponding to a geometric mean density of  $1.0 \times 10^7$ ) for both organisms is required. A mean log density  $<6.0$  or  $>7.0$  invalidates the test. To support products labeled as “disinfectants”, conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbes. The performance standard for both organisms is 0-1 positive carrier out of sixty. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at  $\leq 10$  minutes of contact. For additional microorganisms other than those named as the designated test microorganism(s), refer to Disinfectants for Use on Hard Surface Environments (Additional Microorganisms) section above (test with 5% organic soil).

#### Laundry Sanitizing– Pre-Soak Treatment:

The effectiveness of sanitizers as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations must be substantiated by data derived using the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) modified to include 5% organic soil. Three product samples, representing three different batches, tested at the lower certified limit(s) of the active ingredient(s), should be tested against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (*K. pneumoniae*) (ATCC 4352). *Enterobacter aerogenes* (ATCC 13048) may be substituted for *K. pneumoniae*. Unglazed ceramic tile should be used for the test carrier. Five (5) test carriers and 3 control carriers should be used for each test. According to the ASTM method, “an average of at least  $7.5 \times 10^5$  organisms must have survived the inoculated control squares for the test to be valid.” The performance standard should demonstrate a reduction of  $\geq 99.9$  percent (a  $3\text{-log}_{10}$  reduction) in the number of each test microorganism over the parallel control count in  $\leq 5$  minutes. To be deemed an effective product, the product must pass all tests for the indicated microbes. For additional microorganisms other than those named as the designated test microorganism(s), refer to Sanitizers (For Non-Food Contact Surfaces: Additional Bacteria) section above (test with 5% organic soil).

#### Supplemental Claims:

An antimicrobial agent identified as a “one-step” disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

## **IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY**

The active ingredients' concentrations of **Batch No. 4562-132** were reported to be 3.99% TAED and 17.69% Sodium percarbonate, **Batch No. 4562-143** were reported to be 3.91% TAED and 17.29% Sodium percarbonate, **Batch No. 4699-40** were reported to be 3.97% TAED and 17.41% Sodium percarbonate, and **Batch No. 4779-9** were 4.00% TAED and 17.48% Sodium

percarbonate. The product's Tetraacetythylenediamine (TAED) and Sodium percarbonate nominal concentrations are 4.44% and 18.5%, respectively, and the Lower Certified Limits of the product are 4.00% and 17.58%, respectively.

1. **MRID 49795317 "AOAC Use-Dilution Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 27, 2016. Project Identification No. A19644.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Four batches (Batch# 4562-132, Batch# 4562-143, Batch# 4699-40, and Batch# 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.1 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Batch# 4562-132 was tested on 11/18/15, Batch# 4562-143 was tested on 11/18/15 and 01/06/16, and Batch# 4699-40 was tested on 11/23/15. Additional testing using a higher concentration of active was performed on Batch# 4779-9 on 12/21/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.0-20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (Synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The *Pseudomonas* culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. All three test cultures were diluted with synthetic broth. The culture did not include a 5% organic soil load. Sixty (60) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.6-36.7°C and at 50.1-53.3% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.0-20.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate [on test dates 11/18/15, 11/19/15, 11/23/15, and 01/06/16]; Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate [on test date 12/21/15]). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On

11/21/15, 11/25/15 and 12/23/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37°C for 1-2 days. The cultures from 11/25/15 were refrigerated at 2-8°C for 3 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 6.79 log<sub>10</sub>, for *Salmonella enterica* (ATCC 10708) was 5.84 log<sub>10</sub>, and for *Staphylococcus aureus* (ATCC 6538) was 6.53 log<sub>10</sub>.

#### Note

Amendment I: The lot numbers were to be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562-143, and Lot 4699-40. The following sentence was to be added to the protocol modification section: Each lot was supplied in a 53.4gm dose.

Amendment II: Additional testing on lot 4779-9, with a higher active concentration closer to the lower certified limits specified on the Confidential Statement of Formula, was to be added to this protocol. Lot 4779-9 was tested for *Staphylococcus aureus* (ATCC 6538) only. All other testing parameters documented in the protocol was to be followed.

There were no protocol deviations.

The assay was set up to be run on 3 separate test dates; 11/18/15, 11/19/15, and 11/23/15. Per Sponsor request, additional testing of *Staphylococcus aureus* with a lot containing a higher active concentration was added to the protocol (see Amendment 2) and tested on 12/14/15. **The test from 12/14/15 was invalid because the neutralization confirmation control results did not meet validity criteria.** The invalid data from 12/14/15 can be found in Attachment I. The invalid portion of the assay was repeated on 12/21/15. That data is valid and is contained in the body of this report. **On 11/19/15, the *Salmonella enterica* portion of the assay was invalid due to the carrier population control being under the minimum requirement.** This portion of the assay was repeated on 01/06/15. The invalid data from 11/19/15 can be found in Attachment II. The data from 01/06/15 is considered valid and is contained in the body of this report.

## **2. MRID 49795318 “AOAC Use-Dilution Method,” Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19755.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.2 (copy provided). The test substances were diluted using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by

combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. The culture did not include a 5% organic soil load. Ten (10) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.7°C and at 52.9 % relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.45 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

### **3. MRID 49795319 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19752.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 21.0°C in a relative humidity of 35.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium

(MEM) supplemented with 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, and 2µg/mL TPCK-Trypsin. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for 2009-H1N1 Influenza A virus was 5.75 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

#### **4. MRID 49795320 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19753.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRG85090815.HSV1.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity

(TCID<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 4.50 log<sub>10</sub>.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**5. MRID 49795321 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19771.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titrated by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as -log<sub>10</sub> of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.00 log<sub>10</sub>.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

6. **MRID 49795322 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19772.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titrated by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was 10% Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as -log<sub>10</sub> of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.00 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

The test was originally run on 12/10/15. **The dried virus control (DVC) did not achieve 4.0 log growth**, as required for a valid study. The assay was re-run on 01/04/16. The assay from 01/04/16 was valid and is included in the body of this report. Invalid data from 12/10/15 can be found in Attachment I.

**7. MRID 49795323 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19736.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>. Five (5) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 28.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as -log<sub>10</sub> of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/200µL) obtained for Human Immunodeficiency virus type 1 was 5.50 log<sub>10</sub>.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**8. MRID 49795324 “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)”, Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 11, 2016. Project Identification No. A19683.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product,

Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Staphylococcus aureus* culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 21.0 mL of culture was concentrated to 3.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 29% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Lethen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10<sup>9</sup>) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/3/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.26 x 10<sup>6</sup> CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 4.07 x 10<sup>6</sup> CFU/carrier.

#### Note

Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.

No protocol deviations occurred during this study.

- 9. MRID 49795325 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 08, 2016. Project Identification No. A19767.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services

Protocol No. SRC85090815.NFS.2 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 21 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 31% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Lethen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was  $2.04 \times 10^5$  CFU/carrier.\

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**10. MRID 49795326 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 12, 2016. Project Identification No. A19691.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an

initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10  $\mu$ L) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24 $\pm$ 2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for  $\geq$ 15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0  $\mu$ L) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated cotton carriers were dried for 20-21 minutes at 35-37°C (35.9-36.1°C) and 40-41% relative humidity with the Petri dish lids intact. The inoculated polyester carriers were dried for 24-26 minutes at 35-37°C (35.9-36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25-37% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Lethen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate for testing against *S. aureus*. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48 $\pm$ 4 hours. Following incubation, the subcultures were visually enumerated. On 12/10/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Staphylococcus aureus* (ATCC 6538) was 1.20 x 10<sup>6</sup> CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 3.09 x 10<sup>7</sup> CFU/carrier. The reported average carrier population control on polyester for *Staphylococcus aureus* (ATCC 6538) was 1.91 x 10<sup>6</sup> CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 2.82 x 10<sup>7</sup> CFU/carrier.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**Testing on November 30, 2015 resulted in a carrier population control failure for *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers.** Testing of *Staphylococcus aureus* from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Staphylococcus aureus* and the testing for *Klebsiella pneumoniae* performed on November 30, 2015 are considered valid and presented in the body of the report. Testing

of Capricorn, Lot 4562-132, Lot 4562-143 and Lot 4699-40 against *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers was repeated on December 8, 2015. Data from this test date is considered valid and presented in the body of the report.

**11. MRID 49795327 “Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)”, Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19902.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The “initial broth suspension” was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 16% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Lethen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Escherichia coli* 0157:H7 (ATCC 43888) was  $1.74 \times 10^5$  CFU/carrier and the reported average carrier population control on polyester for the microorganism was  $1.48 \times 10^7$  CFU/carrier.

Note

Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

**12. MRID 49795328 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces", Test Organisms: *Salmonella enterica* (ATCC 10708), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 26, 2016. Project Identification No. A19900.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.3 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was centrifuge concentrated at 3510 RPM for 10 minutes. A total of 18.0mL of culture was concentrated to 3.6mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36.5°C) and 41% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (19°C) and 15% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10<sup>6</sup>) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Salmonella enterica* (ATCC

10708) was  $1.86 \times 10^6$  CFU/carrier and the reported average carrier population control on polyester for the microorganism was  $1.10 \times 10^7$  CFU/carrier.

Note

Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

**13. MRID 49795329 “EPA Hard Surface Mildew-Fungistatic Test”, Test Organisms: *Aspergillus niger* (ATCC 6275), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19759.**

This study was conducted against *Aspergillus niger* (ATCC 6275). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.MSTAT (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was  $1.2 \times 10^8$  CFU/mL. The suspension was added to a sterile tissue grinder and macerated to break up spore chains at the time of harvesting. The macerated conidial suspension was standardized to contain an approximate target of  $5 \times 10^6$  conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. A 1.0mL aliquot of this suspension was added to 20.0mL of sterile Czapek's solution. A 1.00mL aliquot of FBS was added to 19.0mL of prepared Czapek/organism suspension to yield a 5% Fetal Bovine Serum organic soil load. One inch by one inch glazed ceramic tiles were sterilized for  $\geq 2$  hours at  $\geq 180^\circ\text{C}$  in a hot air oven and were used as carriers. For each lot of the prepared test substance, the surfaces of 10 carriers were treated by immersing the carriers in the test substance until completely covered. The carriers were removed from the test substance and were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 12 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes (10 carriers total) and dried for 12 minutes at 35-37°C with the lids ajar alongside the test carriers. Following the initial drying period, an atomizer was used to spray the surface of each test carrier and control carrier with the *Aspergillus niger* conidia-Czapek suspension. Approximately 2 sprays were used to apply the test organism. The atomizer was periodically mixed to agitate the culture during inoculation. Carriers contained in Petri dishes were returned to a 35-37°C incubator and dried with the lids slightly ajar for 18 minutes until visibly dry. Each carrier (sprayed side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. The purity control was incubated for 44-76 hours at 25-30°C. All test and control carriers were examined after 7 days of incubation. The absence of fungal growth on all carriers is the criterion for determining the effectiveness of the test product. No visual growth was evident at the end of the 7 days on test carriers therefore a magnified examination was performed. To be considered a valid test, each untreated control carrier must be at least 50% covered with fungal growth after the 7 days. Controls included sterility, purity, and untreated control carriers. The visual evaluation of control carriers was reported as passing.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**14. MRID 49795330 “Fabric Mildew-Fungistatic Test”, Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333), for Capricorn, EPA Reg. No. 10772-EG, by Matthew Sathe, B.S. Study conducted at Accuratus Lab Services. Study completion date – February 5, 2016. Project Identification No. A19758.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FMSTAT (copy provided). The test substance was prepared by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was  $1.2 \times 10^8$  CFU/mL. The conidial suspension was standardized to contain an approximate target of  $5 \times 10^6$  conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. The *Penicillium variable* conidial suspension was prepared by inoculating 30 Sabouraud Dextrose agar plates (also known as Emmons agar) and incubating at 25-30°C for 11 days (see Protocol Deviation). Following incubation, 3.0 mL of sterile saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) was added to each plate harvested. The growth was harvested from the agar surface using a cell scrape. The harvested growth was transferred to a sterile vessel containing sterile beads and was swirled thoroughly. The culture was then filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The conidial count was  $9.8 \times 10^8$  CFU/mL. The conidial suspension was standardized to contain an approximate target of  $5 \times 10^6$  conidia per mL by combining 1.00 mL of unadjusted culture with 49.0 mL of 0.85% saline. Fabric carriers were cut as approximately 25mm by 75mm strips from 136 to 203g/m<sup>2</sup> (4 to 6 oz/yd<sup>2</sup>) cotton muslin and were autoclave. The sterilized fabric carriers were saturated with sterile glycerol nutrient solution by soaking the carriers for approximately three minutes until saturated. The excess liquid was squeezed out and the fabric carriers were allowed to dry prior to use as carriers. For each lot of the prepared test substance, 10 test carriers were treated by dipping the carriers in the test substance. The carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at room temperature (23.3°C) for 37 minutes until dry. Equal volumes (10.0mL) of each well-mixed conidial suspension were combined within a DeVilbiss atomizer. One mL was removed and a 1.00 mL aliquot of FBS was added to 19.0 mL of the combined organism suspension to yield a 5% Fetal Bovine Serum soil load. Both sides of each fabric test carrier strip was lightly sprayed using approximately 6 sprays. The culture was mixed periodically within the atomizer during spraying. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 3 days at 25-30°C. These subcultures were refrigerated for 2 days at 2-8°C prior to examination. Observations were made and recorded every 7 days for four weeks. The presence or absence of observable mold on the test carriers was the criterion for determining the effectiveness of the test product. Where no growth was visually evident at each weekly observation, a magnified

examination was conducted to confirm the absence or establish the presence of sub-visual growth. Controls included sterility, purity, initial suspension, and untreated control carrier. The visual evaluation of control carriers was reported as passing. To be considered a valid control, each untreated control carrier must be covered with at least 50% of fungal growth over the total surface area after 7 days of incubation.

Note

250 mL French square bottles containing 10 mL of deionized water were used to incubate the samples in this study. This is a modification of the method and was performed because of apparatus availability. Despite this modification, samples were incubated in a humid environment as required by the method and can be hooked so that the bottom ends of the attached fabric samples are about 13 mm above the water level as required by the method.

There were no protocol amendments.

Protocol Deviation:

The protocol states *Penicillium variable* will be prepared by incubating Sabouraud Dextrose agar plates for 7-10 days. **In testing, the *Penicillium variable* culture was inadvertently incubated for 11 days.** Since the culture met the control acceptance criteria outlined in the protocol, this protocol deviation has no impact on the outcome of the study.

- 15. MRID 49795331 “AOAC Use-Dilution Method,” Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19659.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Three batches (Batch# 4562-132, Batch# 4562-143, and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.4 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Batch# 4562-132 was tested on 11/25/15, Batch# 4562-143 was tested on 11/23/15, and Batch# 4699-40 was tested on 11/24/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20±1°C (19.5-20.0°C) water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. Each test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The *Pseudomonas* culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. A 3.5 mL aliquot of FBS was added to 66.5 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sixty (60) stainless

steel penicylinders per product lot were immersed for in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.0-36.7°C) and at 50.6-52.5% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 14.5 minutes at 19.5-20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On 11/25/15, 11/26/15, and 11/27/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37°C for 1-2 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 7.09 log<sub>10</sub>, for *Salmonella enterica* (ATCC 10708) is 6.07 log<sub>10</sub>, and for *Staphylococcus aureus* (ATCC 6538) was 6.49 log<sub>10</sub>.

#### Note

##### Protocol Amendments:

Amendment 1: Per Sponsor request, the exposure time will be changed from 15 minutes to 14.5 minutes.

Amendment 2: Per Sponsor request, the following reference will be added to the protocol; U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2400: Disinfectants and Sanitizers for Use on Fabrics and Textiles- Efficacy Data Recommendations, December 21, 2012.

Amendment 3: Per Sponsor request, the lot numbers will be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562- 143, and Lot 4699-40. Per Sponsor request, the following sentence will be added to the protocol modification section: Each lot was supplied in a 62.4gm dose.

##### Protocol Deviation:

Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly. This deviation has no impact on the overall Intent and purpose of the study.

**Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly (see protocol deviation).** Data from 11/25/15 is valid and is presented in the report. See Attachment I for invalid data from 11/19/15.

- 16. MRID 49795332 “AOAC Use-Dilution Method,” Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19757.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.5 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted by combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. A 1.5 mL aliquot of FBS was added to 28.5 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.7°C) and at 50.2% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.5°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.58 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**17. MRID 49795333 “AOAC Use-Dilution Method,” Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19756.**

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.6 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an

initial 10 mL tube of growth medium (Nutrient broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. A 1.5 mL aliquot of FBS was added to 28.5 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.6-36.7°C) and at 52.1% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Klebsiella pneumoniae* (ATCC 4352) was 7.07 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

#### **18. MRID 49795334 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31, 2015. Project Identification No. A19760.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 26.6% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.0°C). Just prior to the end

of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures ( $10^{-1}$  dilution). To aid in the removal of the cytotoxic effects to the cell cultures the  $10^{-1}$  dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ( $10^{-1}$  dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2.5 µg/mL TTPCK-trypsin, 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for 2009-H1N1 Influenza A virus was 5.25 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**19. MRID 49795335 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19761.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). The stock virus culture contained 5% fetal bovine serum as the organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HSV1.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 51% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the  $10^{-1}$  dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ( $10^{-1}$  dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL

gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 5.25 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**The initial assay performed on December 9, 2015, was repeated on January 4, 2016, to recover at least 4 log<sub>10</sub> of infectivity from the dried virus control as required for a valid test.** See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.

**20. MRID 49795336 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31 2015. Project Identification No. A19770.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titrated by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60

minutes at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.75 log<sub>10</sub>.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**21. MRID 49795337 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19769.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as  $-\log_{10}$  of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and

neutralization. The dried virus control (in TCID<sub>50</sub>/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.25 log<sub>10</sub>.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**The initial assay performed on December 10, 2015, was repeated on January 4, 2016, to recover at least 4 log<sub>10</sub> of infectivity from the dried virus control as required for a valid test and to demonstrate neutralization in the non-virucidal level control. See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.**

**22. MRID 49795338 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces”, Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19728.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>. The stock virus culture contained 5% fetal bovine serum as the organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.5°C in a relative humidity of 26.5% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.5°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the 10<sup>-1</sup> dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates (10<sup>-1</sup> dilution) were then titrated by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as -log<sub>10</sub> of the 50 percent titration endpoint for infectivity (TCID<sub>50</sub>) or cytotoxicity (TCD<sub>50</sub>), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in TCID<sub>50</sub>/200µL) obtained for Human Immunodeficiency virus type 1 was 5.75 log<sub>10</sub>.

#### Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**23. MRID 49795339 “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)”, Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19679.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Four batches (Nos. 4562-132, 4562-143, 4699-40, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.5 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The “initial broth suspension” was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10  $\mu$ L) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24 $\pm$ 2 hours using the appropriate growth medium (Nutrient broth). A 48-54 hour culture was vortex-mixed and allowed to settle for  $\geq$ 15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. For testing performed on 11/30/15, the *Staphylococcus aureus* culture was diluted by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. For testing on 12/15/15, the *Klebsiella pneumoniae* culture was centrifuge concentrated at 3500 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1” x 1” unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0  $\mu$ L) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Lethen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48 $\pm$ 4 hours. Following incubation, the subcultures were visually enumerated. On 12/2/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.15 x 10<sup>6</sup> CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 1.51 x 10<sup>6</sup> CFU/carrier.

#### Note

Protocol Amendments:

1.
  - a. Per Sponsor's request the protocol is amended to change the exposure time the exposure time from 10 minutes to 9.5 minutes.
  - b. Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.
2. Per Sponsor's request the protocol is amended to change Lot 4562-143 to Lot 4779-9 for repeat testing against *Klebsiella pneumoniae* (ATCC 4352).

Protocol Deviation:

Per the protocol, the Test Culture Titer (TOT) and the Neutralizer Toxicity Treatment (NTT) are to be completed using 25 mL of sterile diluent/neutralizer. The TOT and NTT controls were completed using 30 mL of sterile diluent/neutralizer to make a direct comparison to the test and the amounts used in testing.

**Testing performed on November 30, 2015 resulted in a carrier population control failure for *Klebsiella pneumoniae*.** Testing against *Klebsiella pneumoniae* (Lot 4562-132, Lot 4562-143 and Lot 4699-40) from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Klebsiella pneumoniae* performed on November 30, 2015 were deemed acceptable and valid and are presented in the body of the report. Testing of *Klebsiella pneumoniae* was repeated on December 15, 2015 against Capricorn Lot 4562-132, Lot 4699-40 and Lot 4779-9 (see Amendment 2). Neutralization confirmation controls for Lot 4779-9 were also performed on December 15, 2015. All testing performed on December 15, 2015 is considered valid and presented in the body of the report.

**24. MRID 49795340 “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)”, Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19749.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.6 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The “initial broth suspension” was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Synthetic broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1” x 1” unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual

sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 23% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was 7.41 x 10<sup>5</sup> CFU/carrier.

#### Note

Protocol Amendments:

No protocol amendments were required for this study.

Protocol Deviations:

- Per the protocol, inoculated carriers are to be dried for 20-40 minutes until visibly dry. The carriers were dried for a full 40 minutes, but were still not visibly dry when used in testing.
- Per the protocol and protocol modifications, the test substance was to be used within 40 minutes following the mixing of the test substance. The test substance was inadvertently used 13-14 minutes after the expiration time.

**Testing performed on December 9, 2015 was completed using carriers that were not visibly dry (see Protocol Deviation).** Therefore, data from this test date is invalid and presented in Attachment I. Due to the carriers being wet, testing was repeated in its entirety on December 21, 2015. Data from this test date is valid and presented in the body of this report.

## **V. RESULTS**

### **1. Hard Non-Porous Surface Bactericidal Disinfectant (62.4g/1L):**

Contact Time	MRID No.	Organism	No. Carriers Exhibiting Growth/Total Carriers				Carrier Population (Log <sub>10</sub> CFU/Carrier)
			Batch #4562-132	Batch #4562-143	Batch #4699-40	Batch #4779-9	
9.5 minutes	49795318	<i>Escherichia coli</i> 0157:H7 (ATCC 43888)	0/10	--	0/10	--	6.45
	49795317	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	2/60	--	6.79
		<i>Salmonella enterica</i> (ATCC 10708)	0/60	0/60	0/60	--	5.84
		<i>Staphylococcus aureus</i> (ATCC 6538)	0/60	<b>7/60</b>	0/60	2/60	6.53

## 2. Hard Non-Porous Surface Virucidal Disinfectant (62.4g/1L):

MRID No.	Contact Time	Organism	Results		
				Batch #4562-132	Batch #4699-40
49795319	4.5 minutes	2009-H1N1 Influenza A Virus (novel H1N1) + 1% FBS	Description	Rep. 1	Rep. 1
			10 <sup>-1</sup> to 10 <sup>-6</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>
			Log <sub>10</sub> Reduction	≥5.25	≥5.25
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.75</sup>	
49795320		Herpes simplex virus type 1 + 1% FBS	10 <sup>-1</sup> to 10 <sup>-4</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>
			Log <sub>10</sub> Reduction	≥4.00	≥4.00
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>4.50</sup>	
49795321		Rotavirus + 1% FBS	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity
			10 <sup>-2</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>
			Log <sub>10</sub> Reduction	≥3.50	≥3.50
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.00</sup>	
49795322		Rhinovirus type 39 + 1% FBS	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity
			10 <sup>-2</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>
			Log <sub>10</sub> Reduction	≥3.50	≥3.50
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.00</sup>	
49795323		Human Immunodeficiency virus type 1 + 5% FBS	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity
			10 <sup>-2</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /200µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>
			Log <sub>10</sub> Reduction	≥4.00	≥4.00
			Dried Virus Control (TCID <sub>50</sub> /200µL)	10 <sup>5.50</sup>	

## 3. Hard Non-Porous Non-Food Contact Surface Sanitizer (62.4g/2L):

Contact Time	MRID No.	Organism	Results			Carrier Population CFU/Carrier (Avg. Log <sub>10</sub> )
			Batch#	CFU/Carrier (Average log <sub>10</sub> )	Percent Reduction	
4.5 minutes	49795324	<i>Staphylococcus aureus</i> (ATCC 6538) + 5% FBS	4562-132	6.17 x 10 <sup>2</sup> (2.79)	>9.99	1.26 x 10 <sup>6</sup> (6.10)
			4562-143	6.03 x 10 <sup>2</sup> (2.78)	>9.99	
			4699-40	5.89 x 10 <sup>2</sup> (2.77)	>9.99	
			4562-132	<2.51 x 10 <sup>1</sup> (<1.40)	>9.99	4.07 x 10 <sup>6</sup> (6.61)

		<i>Klebsiella pneumoniae</i> (ATCC 4352) + 5% FBS	4562-143	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	
			4699-40	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	
	49795325	<i>Escherichia coli</i> 0157:H7 (ATCC 43888) + 5% FBS	4562-132	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$2.04 \times 10^5$ (5.31)
			4699-40	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	

#### 4. Soft, Non-Food Contact Surface Sanitizer (62.4g/L)

Contact Time	MRID No.	Organism	Results				
			Batch#	100% Plain Cotton Weave		100% Polyester	
				CFU/Carrier (Average $\log_{10}$ )	Percent Reduction	CFU/Carrier (Average $\log_{10}$ )	Percent Reduction
4.5 minutes	49795326	<i>Staphylococcus aureus</i> (ATCC 6538) + 5% FBS	4562-132	$3.98 \times 10^2$ (2.60)	$>9.99$	$<3.31 \times 10^2$ (2.52)	$>9.99$
			4562-143	$1.66 \times 10^2$ (2.22)	$>9.99$	$<8.32 \times 10^1$ (1.92)	$>9.99$
			4699-40	$<8.71 \times 10^1$ ( $<1.94$ )	$>9.99$	$<3.80 \times 10^1$ ( $<1.58$ )	$>9.99$
		Carrier Population CFU/Carrier (Avg. $\log_{10}$ )		$1.20 \times 10^6$ (6.08)		$1.91 \times 10^6$ (6.28)	
		<i>Klebsiella pneumoniae</i> (ATCC 4352) + 5% FBS	4562-132	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
			4562-143	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
			4699-40	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
		Carrier Population CFU/Carrier (Avg. $\log_{10}$ )		$3.09 \times 10^7$ (7.49)		$2.82 \times 10^7$ (7.45)	
	49795327	<i>Escherichia coli</i> 0157:H7 (ATCC 43888) + 5% FBS	4562-132	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
			4779-9	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
		Carrier Population CFU/Carrier (Avg. $\log_{10}$ )		$1.74 \times 10^5$ (5.24)		$1.48 \times 10^7$ (7.71)	
	49795328	<i>Salmonella enterica</i> (ATCC 10708) + 5% FBS	4562-132	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
			4779-9	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$	$<2.51 \times 10^1$ ( $<1.40$ )	$>9.99$
		Carrier Population CFU/Carrier (Avg. $\log_{10}$ )		$1.86 \times 10^6$ (6.27)		$1.10 \times 10^7$ (7.04)	

### 5. Hard Surface Mildew-Fungistatic (62.4g/L):

Contact Time	MRID No.	Organism	Visual Evaluation		Magnified Evaluation		*Untreated Carrier Results (Pass/Fail)
			Batch #4562-132	Batch #4699-40	Batch #4562-132	Batch #4699-40	
Day 7	49795329	<i>Aspergillus niger</i> (ATCC 6275) + 5% FBS	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers

\*To be considered passing, each control carrier must demonstrate  $\geq 50\%$  coverage at Day 7.

### 6. Fabric Mildew-Fungistatic (62.4g/L):

MRID No.	Organism	Contact Time	Visual Evaluation		Magnified Evaluation		*Untreated Carrier Results (Pass/Fail)
			Batch #4562-132	Batch #4699-40	Batch #4562-132	Batch #4699-40	
49795330	<i>Aspergillus niger</i> (ATCC 6275) & <i>Penicillium variable</i> (ATCC 32333) + 5% FBS	Day 7	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers
		Day 14	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers
		Day 21	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers
		Day 28	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers

\*To be considered passing, each control carrier must demonstrate  $\geq 50\%$  coverage.

### 7. Laundry Presoak Bactericide Disinfectant (62.4g/2L):

Contact Time	MRID No.	Organism	No. Carriers Exhibiting Growth/Total Carriers			Carrier Population (Log <sub>10</sub> CFU/Carrier)
			Batch #4562-132	Batch #4562-143	Batch #4699-40	
14.5 minutes	49795331	<i>Staphylococcus aureus</i> (ATCC 6538) + 5% FBS	2/60	3/60	1/60	6.50
		<i>Pseudomonas aeruginosa</i> (ATCC 15442) + 5% FBS	0/60	0/60	0/60	7.09
		<i>Salmonella enterica</i> (ATCC 10708) + 5% FBS	0/60	1/60	0/60	6.07
15 minutes	49795332	<i>Escherichia coli</i> 0157:H7 (ATCC 43888) + 5% FBS	0/60	--	0/60	6.58

	49795333	<i>Klebsiella pneumoniae</i> (ATCC 4352) + 5% FBS	0/60	--	0/60	7.07
--	----------	--	------	----	------	------

#### 8. Laundry Presoak Virucide Disinfectant (62.4g/2L):

MRID No.	Contact Time	Organism	Results		
				Batch #4562-132	Batch #4699-40
49795334	14.5 minutes	2009-H1N1 Influenza A Virus (novel H1N1) + 5% FBS	Description	Rep. 1	Rep. 1
			10 <sup>-1</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>
			Log <sub>10</sub> Reduction	≥4.75	≥4.75
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.25</sup>	
49795335		Herpes simplex virus type 1 + 5% FBS	10 <sup>-1</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>
			Log <sub>10</sub> Reduction	≥4.75	≥4.75
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.25</sup>	
49795336		Rotavirus + 5% FBS	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity
			10 <sup>-2</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>
			Log <sub>10</sub> Reduction	≥4.25	≥4.25
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.75</sup>	
49795337		Rhinovirus type 39 + 5% FBS	10 <sup>-1</sup> to 10 <sup>-5</sup> dilutions	Complete Inactivation	Complete Inactivation
			TCID <sub>50</sub> /100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>
			Log <sub>10</sub> Reduction	≥4.75	≥4.75
			Dried Virus Control (TCID <sub>50</sub> /100µL)	10 <sup>5.25</sup>	
49795338		Human Immunodeficiency virus type 1 + 5% FBS	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity
			10 <sup>-2</sup> to 10 <sup>-6</sup> dilutions	Complete Inactivation	Complete Inactivation
	TCID <sub>50</sub> /200µL		≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>	
	Log <sub>10</sub> Reduction		≥4.25	≥4.25	
	Dried Virus Control (TCID <sub>50</sub> /200µL)		10 <sup>5.75</sup>		

#### 9. Laundry Presoak Sanitizer (62.4g/2L):

Contact Time	MRID No.	Organism	Results			Carrier Population CFU/Carrier (Avg. Log <sub>10</sub> )
			Batch#	CFU/Carrier (Average log <sub>10</sub> )	Percent Reduction	
9.5 minutes	49795339	<i>Staphylococcus aureus</i> (ATCC 6538) + 5% FBS	4562-132	<3.02 x 10 <sup>1</sup> (<1.48)	>9.99	1.15 x 10 <sup>6</sup> (6.06)
			4562-143	<3.02 x 10 <sup>1</sup> (<1.48)	>9.99	

		4699-40	$<3.47 \times 10^1$ ( $<1.54$ )	$>9.99$	
	<i>Klebsiella pneumoniae</i> (ATCC 4352) + 5% FBS	4562-132	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	$1.51 \times 10^6$ (6.18)
		4699-40	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	
		4779-9	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	
		4562-132	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	
49795340	<i>Escherichia coli</i> 0157:H7 (ATCC 43888) + 5% FBS	4562-132	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	$7.41 \times 10^5$ (5.87)
		4699-40	$<3.02 \times 10^1$ ( $<1.48$ )	$>9.99$	

## VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following microorganisms tested without a 5% organic soil load on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 9.5 minute contact time.

MRID 49795317      *Pseudomonas aeruginosa* (ATCC 15442),  
*Salmonella enterica* (ATCC 10708),  
*Staphylococcus aureus* (ATCC 6538)  
MRID 49795318      *Escherichia coli* 0157:H7 (ATCC 43888)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time.

Cultures included 1% fetal bovine serum as organic soil load:

MRID 49795319      2009-H1N1 Influenza A virus, Novel H1N1, Strain  
A/Mexico/4106/2009 CDC #2009712192  
MRID 49795320      Herpes simplex virus type 1, ATCC VR-733, Strain F(1)  
MRID 49795321      Rotavirus, ATCC VR-2018, Strain WA  
MRID 49795322      Rhinovirus type 39, ATCC VR-340, Strain 209

Cultures included 5% fetal bovine serum as organic soil load:

MRID 49795323      Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>

Recoverable virus titer of at least 4 log<sub>10</sub> were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

3. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum

as organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

MRID 49795324 *Staphylococcus aureus* (ATCC 6538)

*Klebsiella pneumoniae* (ATCC 4352)

MRID 49795325 *Escherichia coli* 0157:H7 (ATCC 43888)

Product demonstrated at least 3 log<sub>10</sub> reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

4. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on soft surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time (using plain cotton weave and polyester as the types of carriers).

MRID 49795326 *Staphylococcus aureus* (ATCC 6538)

*Klebsiella pneumoniae* (ATCC 4352)

MRID 49795327 *Escherichia coli* 0157:H7 (ATCC 43888)

MRID 49795328 *Salmonella enterica* (ATCC 10708)

Product demonstrated at least 3 log<sub>10</sub> reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7 days of incubation.

MRID 49795329 *Aspergillus niger* (ATCC 6275)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

6. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on fabrics when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7, 14, 21, and 28 days of incubation.

MRID 49795330 *Aspergillus niger* (ATCC 6275),

*Penicillium variable* (ATCC 32333)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

7. The submitted efficacy data **did not support** the use of the product, Capricorn, as a laundry presoak disinfectant with bactericidal activity against the following microorganisms, tested

with 5% fetal bovine serum as an organic soil load, on stainless steel penicylinders when diluted using 62.4g of product in 2L of water of up to 100ppm hardness.

In 14.5 minute contact time:

MRID 49795331      *Pseudomonas aeruginosa* (ATCC 15442),  
                             *Salmonella enterica* (ATCC 10708),  
                             *Staphylococcus aureus* (ATCC 6538)

In 15 minute contact time:

MRID 49795332      *Escherichia coli* 0157:H7 (ATCC 43888)  
MRID 49795333      *Klebsiella pneumoniae* (ATCC 4352)

Killing was not observed in the subcultures of the required number of carriers tested against the required number of product lots. Data for *Staphylococcus aureus* (ATCC 6538) did not satisfy the performance standards, which specify that the product should kill all test microorganisms on 59 out of each set of 60 carriers in the specified contact time (Refer to OCSPP 810.2400 section (d)(1)(iii)(B)). Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

8. The submitted efficacy data below **support** the use of the product, Capricorn, as a laundry presoak disinfectant with virucidal activity against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on glass petri dish surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 14.5 minute contact time.

MRID 49795334      2009-H1N1 Influenza A virus, Novel H1N1, Strain  
                             A/Mexico/4106/2009 CDC #2009712192  
MRID 49795335      Herpes simplex virus type 1, ATCC VR-733, Strain F(1)  
MRID 49795336      Rotavirus, ATCC VR-2018, Strain WA  
MRID 49795337      Rhinovirus type 39, ATCC VR-340, Strain 209  
MRID 49795338      Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>

Recoverable virus titer of at least 4 log<sub>10</sub> were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

9. The submitted efficacy data **support** the use of the product, Capricorn, as a presoak sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on unglazed ceramic tiles when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

MRID 49795339      *Staphylococcus aureus* (ATCC 6538)  
                             *Klebsiella pneumoniae* (ATCC 4352)  
MRID 49795340      *Escherichia coli* 0157:H7 (ATCC 43888)

Product demonstrated at least 3 log<sub>10</sub> reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

**VII. LABEL RECOMMENDATIONS (Dilution of product must be done with deionized water or water with up to 100ppm hardness)**

1. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 10-minute contact time with pre-cleaning instructions.

62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

*Pseudomonas aeruginosa* (ATCC 15442),  
*Salmonella enterica* (ATCC 10708),  
*Staphylococcus aureus* (ATCC 6538)  
*Escherichia coli* 0157:H7 (ATCC 43888)

These claims **are supported** by the applicant's data

2. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with virucidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time with pre-cleaning instructions.

62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009  
Herpes simplex virus type 1, ATCC VR-733, Strain F(1)  
Rotavirus, ATCC VR-2018, Strain WA  
Rhinovirus type 39, ATCC VR-340, Strain 209  
Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>

These claims **are supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time.

31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):

*Staphylococcus aureus* (ATCC 6538),  
*Klebsiella pneumoniae* (ATCC 4352),  
*Escherichia coli* 0157:H7 (ATCC 43888)

These claims **are supported** by the applicant's data.

4. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on soft (fabric) surfaces using the following dilution rate in a 5-minute contact time.

62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

*Staphylococcus aureus* (ATCC 6538),  
*Klebsiella pneumoniae* (ATCC 4352),  
*Escherichia coli* 0157:H7 (ATCC 43888),  
*Salmonella enterica* (ATCC 10708)

These claims **are supported** by the applicant's data.

5. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on soft (fabric) surfaces using the following dilution rate for a 28-day contact period.

62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):  
*Aspergillus niger* (ATCC 6275)

These claims **are supported** by the applicant's data.

6. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on hard, non-porous surfaces using the following dilution rate for a 7-day contact period.

62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):  
*Aspergillus niger* (ATCC 6275),  
*Penicillium variable* (ATCC 32333)

These claims **are supported** by the applicant's data.

7. The proposed label claims are not acceptable regarding the use of the product, Capricorn, as a laundry presoak disinfectant against the following organisms for use in laundry using the following dilution rate by total immersion application for a 15-minute contact time.

31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):  
*Pseudomonas aeruginosa* (ATCC 15442),  
*Salmonella enterica* (ATCC 10708),  
*Staphylococcus aureus* (ATCC 6538),  
*Escherichia coli* 0157:H7 (ATCC 43888),  
*Klebsiella pneumoniae* (ATCC 4352),  
2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009,  
Herpes simplex virus type 1, ATCC VR-733, Strain F(1),  
Rotavirus, ATCC VR-2018, Strain WA,  
Rhinovirus type 39, ATCC VR-340, Strain 209,  
Human Immunodeficiency Virus type 1, Strain HTLV-III<sub>B</sub>

These claims **are not supported** by the applicant's data. In addition, product must be approved as a disinfectant with bactericidal activity against the base microorganisms to qualify as a disinfectant with virucidal activity.

8. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak sanitizer against the following organisms for use in laundry using the following dilution rate by total immersion application for a 10-minute contact time.

31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):  
*Staphylococcus aureus* (ATCC 6538)  
*Klebsiella pneumoniae* (ATCC 4352)  
*Escherichia coli* 0157:H7 (ATCC 43888)

These claims **are supported** by the applicant's data.

9. On the proposed label, registrant must remove laundry pre/post-soak disinfection use and all claims associated with pre/post-soak laundry disinfection. Data did not show the required performance level for laundry pre-soak disinfection.

10. On the proposed label, registrant must include the dilution of product in water that has up to 100 ppm Calcium carbonate, which accurately represents the hardness of the water used for testing. Regular tap water contains more than 100 ppm of hard water and cannot be used to dilute the product.
11. On the proposed label, registrant must add pre-cleaning instructions to all application uses on hard, non-porous surfaces (i.e. disinfectant, sanitizer and mildewstat). Registrant must also remove “one-step” claims from these uses. Product was not tested using at least 5% organic soil load for hard, non-porous surface disinfection.
12. On page 3 of the proposed label, under Laundry Sanitization, registrant must specifically instruct users to prepare the solution accordingly using the accurate doses of product in the required amount of water (as tested) for laundry immersion before adding the treated load to the washing machine. The contact time and amount of water to dilute the product generated from washing machines are difficult to measure and monitor if presoak sanitization were to be done inside the washing machines.
13. On the proposed label, registrant must remove all claims against cold viruses and claims concerning cold prevention. Agency’s criteria for this claim requires effectiveness against 2 of the 3 cold-associated viruses, which are Rhinovirus, Coronavirus, and Respiratory Syncytial virus.
14. On page 4 under soft surface sanitization, the term "spot" should be removed from the brackets as it is not optional.
15. On the proposed label, registrant must remove all claims against “black mold”. The microorganisms tested are not considered black mold-associated microorganisms.
16. On page 7 of the proposed label, under “Marketing Claims”, registrant must remove the claim “ready to use”.
17. On the proposed label, registrant must remove all claims concerning “antibacterial protection”.
18. On page 12 of the proposed label, registrant must specify the claim concerning “cross contamination”. Registrant must specify the claim to, “Can help prevent cross-contamination between treated surfaces by [household] bacteria.”
19. On page 13 of the proposed label, registrant must remove the brackets from the word “surfaces” from the claim, “[This product] will help [you] keep your [surfaces] clean [and disinfected]”. This term is not optional.
20. On pages 13 and 14 of the proposed label, remove the "99.99%" claims from multiple locations under the hard, non-porous disinfection section.
21. On page 14 of the proposed label, registrant must remove “more than” from the claim “Kills more than 99.9% of bacteria and viruses”.
22. On page 21, Table 8: Testing and Dilution Type, Fungi must be removed from the Type of Organism column. The name, “Mold and mildew”, is more appropriate according to Agency’s criteria.

23. On the proposed label, registrant must qualify all of the “virus”, “virucide”, and “virucidal” claims with an asterisk or other symbols to refer the claims mentioned to the viruses tested.
24. On the proposed label, registrant must remove all claims against “fungi”, “fungus” and “fungal spores”. Product was not tested against the Agency-required microorganism to qualify for the claims.